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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,817	05/13/2002	Jacques Edouard Germond	112843-039	9937
29174	7590	09/16/2004	EXAMINER	
BELL, BOYD & LLOYD, LLC P. O. BOX 1135 CHICAGO, IL 60690-1165			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,817

Applicant(s)

GERMOND ET AL.

Examiner

Kathleen M Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-24, 26-36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-24, 26-36 and 38 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/20/01 (originally) is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/21/03, 8/18/03</u> . | 6) <input checked="" type="checkbox"/> Other: <u>copies of seq listings</u> . |

DETAILED ACTION

Application Status

1. A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant's submission filed on March 15, 2004 has been entered.

2. In response to the previous Office action on the merits, an Advisory action (January 14, 2004), Applicant filed a request for continued examination (RCE) and an amendment received on March 15, 2004. Applicant also submitted a sequence listing with a subsequent filing on July 1, 2004. Said amendment amended the specification and cancelled Claim 25. Thus, Claims 20-24, 26-36 and 38 are pending in the instant Office action and will be examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the European application 99112471 filed on June 30, 1999 and International Application No. PCT/EP00/05834 filed on June 23, 2000.

Information Disclosure Statement

4. The information disclosure statements filed on July 21, 2003 and August 18, 2003 have been reviewed, and their references have been considered as shown by the Examiner's initials next to each citation on the attached copies.

Compliance with the Sequence Rules

5. By virtue of Applicant's amendment to the specification identifying sequences in the figures, the application now fully complies with the sequence rules. **See "Allowance" below concerning the need to submit a corrected sequence listing.**

Drawings

6. The drawings are considered **informal** for the reasons detailed in the attached copy of PTO Form 948. **Appropriate correction is required in response** to the instant Office action and may not be held in abeyance (see 37 C.F.R. § 1.85(a)).

Withdrawn - Objections to the Specification

7. Previous objection to the specification for being confusing with respect to the sequence listing is withdrawn by virtue of Applicant's amendment to the specification defining each and every SEQ ID NO listed in the sequence listing.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

8. Previous rejection of Claim 25 under 35 U.S.C. § 112, second paragraph, as being indefinite for the "term "catabolite responsive elements" is withdrawn by virtue of Applicant's cancellation of said claim.
9. Previous rejection of Claim 25 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's cancellation of said claim.

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Allowance

10. This application is in condition for allowance except for the following formal matters:

The pending sequence listing contains a typographical error in the amino acid sequence SEQ ID NO:2 that must be corrected to reflect the originally filed sequence listing.

- a) In SEQ ID NO:2, position 126 was originally filed as an arginine (“R” or “Arg”) in both the paper copy and the computer readable form (CRF). See Figure 4, original paper copy of the sequence listing filed by Applicant, and original CRF copy (USPTO print-out attached) filed by Applicant.
- b) In the sequence listing filed on December 15, 2003 in CRF and paper, the “Arg” is changed to an “Asp” for aspartate or “D”. It is noted that the encoding DNA sequence (SEQ ID NO:1) has not been changed. See paper copy and CRF copy (USPTO print-out attached) filed by Applicant on December 15, 2003.
- c) In the sequence listing filed on March 15, 2004, the CRF was defective, but the paper copy perpetuated the error in SEQ ID NO:2 as noted above. See paper copy filed by Applicant on March 15, 2004.
- d) In the sequence listing filed on July 1, 2004 in CRF and paper, the error is again perpetuated. See paper copy and CRF copy (USPTO print-out attached) filed by Applicant on July 1, 2004.

Therefore, Applicant must file a corrected copy of the sequence listing containing 33 SEQ ID NOs, in computer readable form and paper copy, wherein SEQ ID NO:2 is as originally filed (with an Arg at position 126). A statement of sameness and no new matter must accompany the sequence listing.

11. **Prosecution on the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 C.F.R. § 1.111(b) and M.P.E.P. § 707.07(a).

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A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Conclusion

12. Claims 20-24, 26-36 and 38 are allowed. A corrected sequence listing and formal drawings are required in response to the instant Office action so that the application may be allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

September 13, 2004

```

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                                     RBS
121 ATGGCAACGATCAGAGAAGTGGCCAAGGCAGCCGGCGTGTGCGCCAGCGACGGTTTCCCGG
1  M A T I R E V A K A A G V S P A T V S R
           helix          turn          helix
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21  V L N Y D Q T L S V N E A T R Q K I F K

241 ACTGCTGAAGCCATGCACTACCATAAGAGCCGGAAGACCAGAAAGAGCAAGCAAAAGCGC
41  T A E A M H Y H K S R K T R K S K Q K R
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361 ATCAGAACCAGCGCGCAAGCAGAGGCCAAGAAGCAGGGACTTGAAAGCCAGGTCATTAT
81  I R T S A Q A E A K K Q G L E S Q V I Y
421 CCGGCTGATCCTTTGCCGATCCAGCTGCTTAAAGCGGGATTATCATGATTGGCTACCAG
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121 Q Y S P D R L N E V K K S G L P L V F V
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161 Q E A L E V F W G Q G R E R I A L L D G
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181 D L D S N F D K N N L V D F R F R D Y K
▼
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201 K S L A A R G Q Y D P D L V Y V G N F T
781 CCGCAATCTGGCTATGAAGCCATTAAAGAAGCTCTTAAGTCCGGCTCCTTCCCGAAAGCC
221 P Q S G G Y E A I K E A L K S G S F P K A
841 TTGATTGCGGCTAATGACGCCATGGCTATTGGAGCATTGAAGGCCTTTAAAGAAGCTGGA
241 L I A A N D A M A I G A L K A F K E A G
901 ATTAAAGTCCAGAGGACGTCAGTCTGATTTCTTTAATGACACAACGGCAGCAGAATTT
261 I K V P E D V S L I S F N D T T A A E F
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1081 ACAAACCTCGTTTACCGGAATCTTGCCCAAAAGCATAAGGGCATAGAGCATAATAACAG
321 T K L V Y R E S C P K A *
      ⇨
1141 CAAAGAAATAGCTTGGAGATTGATTTCTCCAAGCTATTTTCGTATATATTATGGCTGC
                                     stop asnA
1201 ATTCTGTTGATCATTCTTGGGAATGGGACAGCTTCACGAACGTGGTCCAGCTTGAGATC
1261 CAGGCAATGACCCGTTCAAAG

```

Figure 4:

Nucleotide and amino acid sequences of the *L. delbrueckii* subsp. *lactis* LL44 *lacR* gene. Start (121) and stop (1119) codons are boxed. Putative *lacR* RBS is underlined. The putative rho-independent terminator is underlined by convergent arrows. Stop codons of the beta-galactosidase (*lacZ*) and Asn t-RNA synthetase (*asnA*) genes are boxed. Insertion sequence of ISL3 is represented by a large open arrow. Single base pair deletion (722) in the mutant LZL102 is shown by an arrow head, leading to a premature stop codon (758) underlined.

ORIGINAL



PCT10

RAW SEQUENCE LISTING

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PATENT APPLICATION: US/10/019,817

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 7 expression in bacterial cells
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 C--> 12 <141> CURRENT FILING DATE: 2002-05-13
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 30 gtcttgaact atgaccagac cctgtcggtc aatgaggcaa cgccgagcaa gatattcaaa 240
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98 Tyr Asp Pro Asp Leu Val Tyr Val Gly Asn Phe Thr Pro Gln Ser Gly
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102 225 230 235 240
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10/01 9817

ORIGINAL

SEQUENCE LISTING

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AMENDED ONCE

SEQUENCE LISTING

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<120> The Lactose operon of Lactobacillus delbrueckii and its use for controlling gene transcription and/or expression in bacterial cells

<130> 112843-039

<140> PCT/EP00/05834

<141> 2000-06-23

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<151> 1999-06-30

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<170> PatentIn version 3.2

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7 cells

9 <130> FILE REFERENCE: 112843-039

C--> 11 <140> CURRENT APPLICATION NUMBER: US/10/019,817

C--> 12 <141> CURRENT FILING DATE: 2002-05-13

14 <150> PRIOR APPLICATION NUMBER: 99112471.0

15 <151> PRIOR FILING DATE: 1999-06-30

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19 <170> SOFTWARE: PatentIn version 3.2

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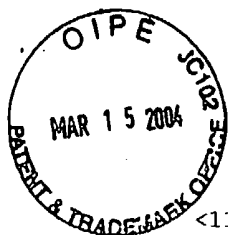
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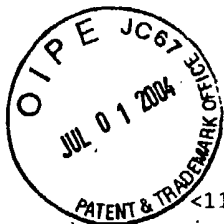
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IFW16

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DATE: 07/08/2004

PATENT APPLICATION: US/10/019,817C

TIME: 12:58:14

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4 <110> APPLICANT: Societe des Produits Nestle S.A.

6 <120> TITLE OF INVENTION: The Lactose operon of Lactobacillus delbrueckii and its use

for

7 controlling gene transcription and/or expression in bacterial
8 cells

10 <130> FILE REFERENCE: 112843-039

C--> 12 <140> CURRENT APPLICATION NUMBER: US/10/019,817C

13 <141> CURRENT FILING DATE: 2002-05-13

15 <150> PRIOR APPLICATION NUMBER: PCT/EP00/05834

16 <151> PRIOR FILING DATE: 2000-06-23

18 <150> PRIOR APPLICATION NUMBER: 99112471.0

19 <151> PRIOR FILING DATE: 1999-06-30

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80 50 55 60
83 Leu Trp Cys Asp Gln Asp Gln Glu Ile Lys Asp Leu Tyr Tyr Tyr Ser
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88 85 90 95
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95 Gly Ile Ile Met Ile Gly Tyr Gln Gln Tyr Ser Pro Asp Asp Leu Asn
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111 Leu Leu Asp Gly Asp Leu Asp Ser Asn Phe Asp Lys Asn Asn Leu Val
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